K111265 1/1

510(k) Summary

AUG - 9 2011

Date Prepared: May 3, 2011

Sponsor:
Metasurg
16350 Park Ten Place, Suite 101
Houston, TX 77084

Company Contact:
Joshua Scott
Phone: (281) 398-5656
Fax: (281) 398-5660

Device Trade Name: Metasurg Subtalar Implant

Classification Name: Smooth & threaded metallic bone fixation fasteners (21 CFR 888.3040, Product Code HWC, Class II)

Common Name: Subtalar Arthrorisis Implant

Substantial Equivalence: Documentation is provided which demonstrates the Metasurg Subtalar Implant to be substantially equivalent to other legally marketed devices.

Device Description: The Metasurg Subtalar Implant is a one-piece device made of titanium intended to be implanted into the sinus tarsi of the foot. The implant is offered in 5 sizes ranging from 8mm to 12mm in diameter. The implant is used in the treatment of the talus relative to the calcaneus.

Intended Usage: The Metasurg subtalar implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

Indications include:

- Severe pronation
- Calcaneal valgus deformity
- Plantarflexed talus
- Failed correction with long term orthotic treatment
- Congenital and painful flatfoot deformity
- Repair of tarsal coalitions
- Subtalar instability
- Posterior tibial tendon dysfunction
- Paralytic flat foot deformity

The Metasurg subtalar implants are intended for single use only.

Material: Titanium Alloy (Ti 6Al-4V ELI)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Metasurg
% Mr. Joshua Scott
16350 Park Ten Place
Suite 101
Houston, Texas 77084

AUG - 9 2011

Re: K111265
Trade/Device Name: Metasurg Subtalar Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: July 19, 2011
Received: July 20, 2011

Dear Mr. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: ~~Pending~~ K111265

Device Name: *Metasurg Subtalar Implant*

Indications for Use:

The Metasurg subtalar implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

Indications include:

- Severe pronation
- Calcaneal valgus deformity
- Plantarflexed talus
- Failed correction with long term orthotic treatment
- Congenital and painful flatfoot deformity
- Repair of tarsal coalitions
- Subtalar instability
- Posterior tibial tendon dysfunction
- Paralytic flat foot deformity

The Metasurg subtalar implants are intended for single use only.

Prescription Use __√__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WIRTE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111256